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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,282	02/25/2002	Shin-ichi Kaiho	KAIHO=3	1523

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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1616

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,282

Applicant(s)

KAIHO ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,9,10,14-17,20,22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8,11-13,18,19,21 and 24-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1-5 and 8-27 are pending in the present application. Claims 3, 4, 9, 10, 14-17, 20, 22 and 23 stand withdrawn from further consideration as being drawn to a nonelected invention/species. Claims 1, 2, 5, 8, 11-13, 18, 19, 21, 24-27 stand rejected as indicated below.

Election/Restriction

3. Applicant's election with traverse of Group II in the reply filed on November 5, 2004 is acknowledged. The traversal is on the ground(s) that that the claimed compounds have the same activity and are androstane derivatives having substituents in the 7- or 11-position. This is not found persuasive because compounds having a 7-substituent are not obvious over compounds having 11-substituent and, thus, search of the claimed compounds would require several different search strategies.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 5, 8, 11-13, 18, 19, 21 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites "provided that when Ra represents a hydrogen atom and Rb and Rc represent $-(C=O)-$, X2 is not a propyl group or an allyl group". Said limitation is not supported by the present specification (see MPEP § 706.03(o)).

6. Claims 1, 2, 5, 8, 11-13, 18, 19, 21 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "X¹ and X² are not a hydrogen atom at the same time " in lines 9-10 on page 3 of the amendment filed November 5, 2004. There is insufficient antecedent basis for this limitation in the claim. The claim does not recite X² can be a hydrogen atom.

Claims 25-27 are indefinite because they are dependent on cancelled claims. Thus, the skilled artisan in the art would be unable to determine the metes and bound of the claimed invention.

Double Patenting

7. Claim 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

8. The rejection of claims 6 and 7 under 35 USC 102(b) over Grunwell et al. ('621) is made moot by the cancellation of the instant claims.
9. The rejection of claims 1, 2, 5, 11-13, 18, 19 and 24-27 under 35 USC 102(b) over Grunwell et al. ('621) is maintained.

Applicant argues the reference does not disclose or suggest that 4-ene-androstane derivatives or 5-ene-androstane derivatives are useful as antiandrogenic agents and pure antagonists. Applicant also argues (a) the properties of the claimed compounds differ from those of the prior art compounds and (b) the claimed invention has been amended to delete compounds having a double bond at the 4-position. Applicant's argument was considered but not persuasive for the following reasons.

In response to applicant's argument regarding the properties of the prior art and claimed compounds, it is noted that the issue is not whether the prior art discloses the same properties as that of the claimed invention. The issue is whether the prior art

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compound is encompassed by the genus set forth by the instant claims since, the skilled artisan would have the reasonable expectation that similar compounds would have similar properties.

As stated in the previous Office Action, the reference teaches the 5-ene compounds are readily isomerized to yield the corresponding 4-ene derivative. The reference teaches compounds such as 17beta-hydroxy-7beta-isopropylandrosta-5-en-3-one, 17beta-hydroxy-7alpha-ethylandrosta-5-en-3-one and 17beta-hydroxy-7beta-ethylandrosta-5-en-3-one and, thus, the 4-ene derivative of said compounds are readily envisaged. The skilled artisan would have the reasonable expectation that the prior art compound(s) encompassed by the claimed genus would have similar properties as set forth by the instant invention.

Applicant also argues the claimed invention has been amended to delete 4-ene derivatives as disclosed by the cited reference. However, formula (I) as recited by the instant claims does not eliminate the prior art compound because the art recognizes the dashed line in the recited formula as an optional saturation such as a double bond. Thus, the prior art compound is encompassed by the claimed genus.

For these reasons and those given in the previous Office Action, the rejection of claims 1, 2, 5, 11-13, 18, 19 and 24-27 under 35 USC 102(b) over Grunwell et al. ('621) is maintained.

10. The rejection of claim of claim 7 under 35 USC 102(b) over Pierdet et al. ('413) is made moot by the cancellation of the instant claim.

11. The rejection of claims 1, 2, 5, 8, 11-13, 18, 19, 21 and 24-27 under 35 USC 102(b) over Pierdet et al. ('413) is maintained.

As indicated above in #9, the issue is not whether the prior art discloses the same properties as that of the claimed invention but whether the prior art compound is encompassed by the genus set forth by the instant claims. As stated in the previous Office Action, the prior art compound is encompassed by the instant claim and, thus, the skilled artisan in the art would have the reasonable expectation that similar compounds would have similar properties including those set forth by the instant invention.

Applicant also argues the claimed invention has been amended to eliminate the prior art compound(s). However, formula (I) as recited by the claimed invention does not eliminate the prior art compound. Although, claim 1 has been amended to delete the language "and the dashed line in combination with the solid line represents the formation of a single bond or a double bond", the structure of formula (I) disclosed by the instant claim encompasses compounds having unsaturation at the 4-position as taught by Pierdet et al.

For this reason and those given in previous Office Action, the rejection of claims 1, 2, 5, 8, 11-13, 18, 19, 21 and 24-27 under 35 USC 102(b) over Pierdet et al. ('413) is maintained.

12. The rejection of claims 6 and 7 under 35 USC 102(b) over Labrie et al. ('375) is made moot by the cancellation of the instant claims.

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13. The rejection of claims 1, 2, 5, 8, 11-13, 18, 19 and 24-27 under 35 USC 102(b) over Labrie et al. ('375) is withdrawn.

14. Claims 1, 2, 5, 8, 11-13, 18, 19, 121 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by De Larminat et al.

De Larminat et al. teach compounds such as 17 β -(acetyloxy)-3-oxo-androstane-7 α -undecanoic acid and 17 β -hydroxy-3-oxo-androstane-7 α -undecanoic acid (see attached Abstract). The compounds and composition taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

15. The rejection of claim 7 under 35 USC 103(a) over Grunwell et al. ('621) is made moot by the cancellation of the instant claim.

16. The rejection of claims 1, 2, 5, 8, 11-13, 18, 19 and 24-27 under 35 USC 103(a) over Grunwell is maintained.

Applicant's argument and the examiner's response are as indicated above in #9.

For these reasons and those given in previous Office Action, the rejection of claims 1, 2, 5, 8, 11-13, 18, 19 and 24-27 under 35 USC 103(a) over Grunwell is maintained.

17. The rejection of claim 7 under 35 USC 103(a) over Pierdet et al. ('413) is made moot by the cancellation of the instant claim.

18. The rejection of claims 1, 2, 5, 8, 11-13, 18, 19, 21 and 24-27 under 35 USC 103(a) over Pierdet et al. ('413) is maintained.

Applicant's argument and the examiner's response are as indicated above in #11.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

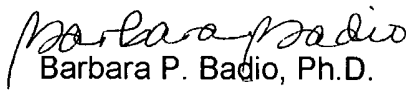
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Telephone Inquiry

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
January 6, 2005